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| 09/916,858  | 07/27/2001  | Mark C. Shults       | 1146-4DIV/CIP 2     | 1611             |
| 20995   | 7590        | 03/22/2004           | EXAMINER            |                  |
| KNOBBE MARTENS OLSON & BEAR LLP<br>2040 MAIN STREET<br>FOURTEENTH FLOOR<br>IRVINE, CA 92614 |             |                      | NASSER, ROBERT L    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3736                | 8                |

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/916,858

Applicant(s)

SHULTS ET AL.

Examiner

Robert L. Nasser

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-19, 21-23 and 25-43 is/are rejected.
- 7) ☒ Claim(s) 13, 14, 20 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23 and 25-43, drawn to a method and device for measuring an analyte in biological fluid, classified in class 600, subclass 345.
- II. Claim 24, drawn to a combined angiogenic/bioprotective membrane, classified in class 204, subclass 403.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the angiogenic/bioprotective membranes are not combined. The subcombination has separate utility such as a measuring method for measuring tissue glucose levels.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Laura Johnson on February 14, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-23 and 25-43. Affirmation of this election must be made by applicant in

replying to this Office action. Claim 24 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Before applying art, the examiner notes that to the best of the examiner's understanding, the term "composite" membrane means a membrane having two contiguous layers.

In addition, the examiner notes that based on this interpretation, it is the examiner's opinion that claims 1-3, 8-12, 15-17, 20, 22, 23, and 25-31 find support in the parent applications, 09/447227 and 08/811473, and therefore are entitled to the filing date of March 4, 1997.

However, it is the examiner's position that claims 4-7, 13, 14, 18, 19, 21, and 32-43 do not find support in the parent applications, and therefore have the filing date of this application, or July 27, 2001.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 17, 20, 22, 23, 27, 28, and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6001067. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are merely broader versions of the patented claims, and, as such, are covered by the patented claims.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/447227. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims and the pending claims cover similar inventions.

The examiner notes that the claims of 09/447227 are not available at this point in time. However, to the best of the examiner's recollection, the claims are subject to a double patenting rejection. This rejection will be reevaluated when the patented claims come available.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/489588. Although the conflicting claims are not identical, they are

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not patentably distinct from each other because the current claims and the pending claims cover similar inventions.

The examiner notes that the claims of 09/489588 are not available at this point in time. However, to the best of the examiner's recollection, the claims are subject to a double patenting rejection. This rejection will be reevaluated when the patented claims come available.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 8 and 32-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 7 and 8 recite that the biostable layer has a tissue interface. The sensor interface is defined in the specification as a region that contacts the tissue. The only disclosed biostable layer is the bioprotective layer. However, applicant has stated that the angiogenic layer is the outermost layer of the membrane. Therefore, the bioprotective layer does not have a sensor interface and the claims and the specification are contradictory. Claims 32-43 lack enablement in that they contradict the specification. Claims 32 recites that the bioprotective layer has a tissue interface. The

sensor interface is defined in the specification as a region that contacts the tissue. However, applicant has stated that the angiogenic layer is the outermost layer of the membrane. Therefore, the bioprotective layer does not have a sensor interface and the claims and the specification are contradictory. Clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 is rejected in that there is no antecedent basis for the sensor interface.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 32, 35, 36, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Ballerstadt et al. Ballerstadt shows a device with housing having a composite membrane made up of bioprotective layer 215 and angiogenic layer 213 (see column 5, line 31), which is on the tissue interface of layer 215. The device further includes concanavalin A immobilized therein.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-12, 17, 19, 22, 23, 25-34 and 37-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blubaugh, Jr. et al 5964993 in view of Picha. Blubaugh Jr. et al shows a device having a housing having an outer membrane 12 that is a bioprotective membrane which is impermeable to microphages (see column 5, lines 48-51) and has a pore size from 0.01 to 0.1 microns, and an inner membrane 14 that functions as an interference layer ( see column 5, lines 13-42) to provide a controlled volume to a sensor 16 for measuring glucose. The device does not have an angiogenic layer. However, Picha teaches that using an angiogenic layer surrounding an implantable sensor improves the accuracy of the implantable sensor. Hence, it would have been obvious to modify Blubaugh Jr. to use the angiogenic layer, so as to improve the overall accuracy of the device. As such, the angiogenic layer on the bioprotective membrane 12 are a composite membrane. Claims 3-6, 9, 10, 19, and 38-43 are rejected in that applicant has not stated that the particular materials used for the layers are for a specific purpose or that the materials used solve a stated problem. Indeed, applicant notes that many materials may be used for each of the layers. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for use. Claims 22 and 23 are rejected in that Blubaugh includes a



radio telemetric device (see column 9, lines 34-35). With respect to claim 25, the combination teaches the method except for the length of implantation. However, it is the examiner's position that the addition of the angiogenic layer would enable sensing for long periods including the recited period. Claims 26-31 are rejected in that Blubaugh shows the method.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blubaugh jr. et al in view Picha, as applied to claims 1-6, 8-12, 17, 19, 22, 23, 25-34 and 37-43 above, further in view of Van Antwerp et al. Van Antwerp et al shows a device for measuring glucose that uses an optical absorbance sensor rather than an electrochemical sensor. Hence, it would have been obvious to modify the above combination to use such an absorbance sensor, as it is merely the substitution of one known sensor for another.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blubaugh jr. et al in view Picha, as applied to claims 1-6, 8-12, 17, 19, 22, 23, 25-34 and 37-43 above, further in view of Allen et al. Allen shows a polyurethane based bioprotective membrane. Hence, it would have been obvious to modify the Blubaugh to use the membrane of Allen, as it is merely the substitution of one known equivalent membrane for another.

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blubaugh jr. et al in view Picha, as applied to claims 1-6, 8-12, 17, 19, 22, 23, 25-34 and 37-43 above, further in view of Cerami. Cerami shows an alternate glucose sensor that uses a concanavalin A as a reverse binding agent for glucose. Hence, it

would have been obvious to modify the above combination to use the sensor arrangement of Cerami, as it is merely the substitution of one known equivalent for another.

Claims 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballerstadt et al. Claims 38-43 are rejected in that applicant has not stated that the particular materials used for the layers are for a specific purpose or that the materials used solve a stated problem. Indeed, applicant notes that many materials may be used for each of the layers. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for use.

Claims 13, 14, 20, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 13 and 14 define over the art of record in that none of the art shows a metal film on the side of the interference layer distal to the sensor. Claims 20 and 21 define over the art in that none of the art shows an angiogenic layer and a material for securing the device to biological tissue, as claimed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Colvin Jr. et al shows a similar device to applicant's.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN  
March 15, 2004

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